



CliniSorb Sutures

Description

CliniSorb is a synthetic absorbable braided sterile surgical suture composed of homopolymers of glycolide (100%). CliniSorb is dyed violet with D & C violet No.2. CliniSorb meets all the requirements established by the B.P., U.S.P. and E.P.

Indications

CliniSorb is indicated for soft tissue approximation and/or ligation, including use in ophthalmic procedures, but not for use in cardiovascular and neurological procedures.

Actions

CliniSorb elicits a minimal acute inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue. Progressive loss of tensile strength and eventual absorption of CliniSorb Synthetic Absorbable Sutures occurs by means of hydrolysis, where the polymer degrades to glycolic acid which is subsequently absorbed and metabolized by the body. Absorption begins as a loss of tensile strength without appreciable loss of mass. Implantation studies in animals indicate that CliniSorb (2USP) retains approximately 70% of its tensile strength at 2 weeks post-implantation, with approximately 40 % remaining at three weeks and 5% at week 4. Absorption of Absorbable Synthetic Suture is essentially complete within 60 days

Contra-Indications

This suture, being absorbable, should not be used where extended approximation of tissue is required.

Warning

As with any foreign body, prolonged contact of this or any other suture with salt solutions such as those found in the urinary tract, may result in calculus formation. Users should be familiar with surgical procedures and techniques involving absorbable sutures before employing CliniSorb synthetic absorbable suture for wound closure, as a risk of wound dehiscence may vary with the site of application and suture material used. Acceptable surgical practice should be followed with respect to drainage and closure of contaminated or infected wounds. The use of this suture may be inappropriate in patients suffering from conditions that may delay wound healing. As this is an absorbable suture material, the use of supplemental non absorbable sutures should be considered by the surgeon in the closure of sites undergoing expansion, stretching or distension, or which may require additional support.

Precautions

Under some circumstances, notably orthopaedic procedures, immobilisation by external support may be employed at the discretion of the surgeon. Skin sutures which must remain in place longer than seven days may cause localised irritation and should be snipped off or removed as indicated. In handling this or any other suture material care should be taken to avoid damage. Avoid crushing or crimping damage due to the application of surgical instruments, such as forceps or needle holders. Adequate knot security requires the accepted practice of flat, square ties, with additional throws as warranted by the surgical circumstances and experience of the surgeon. To avoid damage to needle points and swage areas, grasp the needle in an area one-third (1/3) to one-half(1/2) of the distance from the swaged end to the point. Reshaping needles may cause them to loose strength and be less resistant to bending and breaking. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" container.

Sterility

CliniSorb sutures are sterilized by Ethylene oxide gas. Do not use if package is opened or damaged. Discard opened unused sutures.

Storage

Recommended storage conditions: between 15°C to 30°C, away from direct heat. Do not use after expiry date.

Adverse Reactions

Potential Adverse effects

- Infection
- Dehiscence with need for retreatment
- Acute inflammation

These reactions may occur in patients who are hypersensitive to the material

Broken needles may result in extended or additional surgeries or residual foreign bodies. Inadvertent needle sticks with contaminated surgical needles may result in transmission of blood-borne pathogens.

How supplied

CliniSorb Synthetic Absorbable Braided Suture is available in sizes 6/0 through 2, undyed or dyed violet with D&C violet No.2 and coated. The suture is supplied in non-needed standard lengths (ligatures) or attached to various needle types in boxes of one dozen.



CLINISUT (PTY) LTD
25 Harrower Road
North End
Port Elizabeth, 6001
Republic of South Africa

Date: 30 Sept.2016
Revision: 5

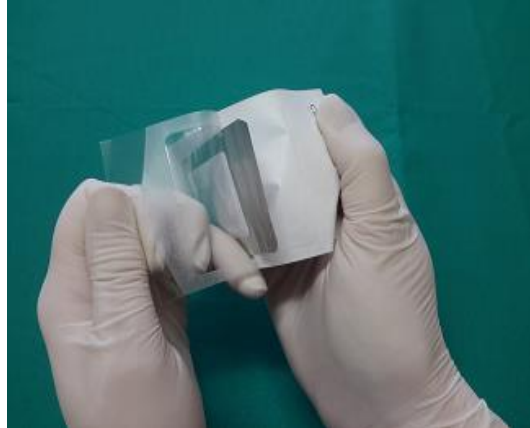
CP3.1 SF4(2)

INSTRUCTIONS FOR OPENING OF CLINISORB SUTURE

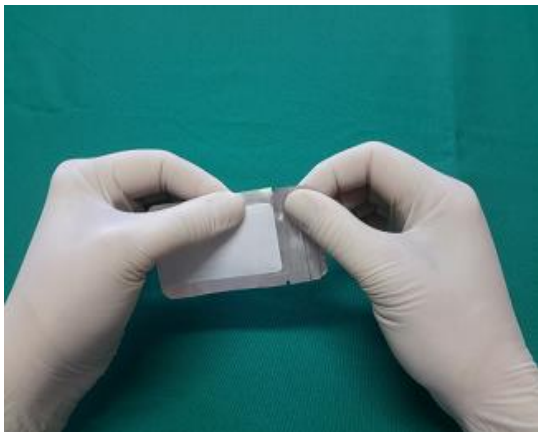
1. Hold suture facing you with opening on right side.



2. Open outer pouch by pulling it apart until inner pouch is exposed and remove.



3. Open foil pouch at tearing notch.



4. Tear open so that inner winding pouch can be removed.



5. Remove inner winding pouch to expose suture.



6. Secure needle in needle holder and pull out of winding pouch



The suture is now ready for use



CliniSorb Sutures

